IITED STATES PATENT AND TRADEMARK OFFICE

In re application of Confirmation No. 9421

Reynir EYJOLFSSON Attorney Docket No. 2004 1082A

Serial No. 10/501,454 Group Art Unit 1616

Filed July 14, 2004 Examiner Andriae M. Holt

FORMULATIONS OF QUINAPRIL

Mail Stop: RCE AND RELATED ACE INHIBITORS

REPLY SUBMITTED CONCURRENTLY WITH RCE

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

TO CHARGE ANY DEFICIENCY IN THE FEE FOR THIS PAPER TO DEPOSIT ACCOUNT NO. 23-0975.

THE COMMISSIONER IS AUTHORIZED

Sir:

In accordance with the RCE submitted herewith, the amendment filed April 25, 2008 will now be entered and considered by the Examiner.

On the Continuation sheet attached to the Advisory Action mailed May 21, 2008, the Examiner states that less than 5wt% of a saccharide compound, in claim 1, continues to read on the rejected claims (the Examiner confirmed during a telephone discussion with Applicants' attorney that she meant to indicate that this reads on the prior art), since less than 5 wt% includes the lower limit of 0 as taught by the prior art.

However, considering the prior art as a whole, Applicants respectfully submit that the presently claimed invention, as set forth in amended claim 1, is not suggested by the prior art. As Applicants have previously noted, the rejections under 35 U.S.C. §103(a) are not based on Harris et al. alone (Example D of this reference discloses a composition with no saccharide), but rather, are based on a combination of Example D of Harris et al. with the Daniel et al. reference. So it is not simply a question of whether or not Harris et al. suggests the presently claimed invention. Rather, the issue is whether or not a combination of Harris et al. with Daniel et al. suggests the invention. In this regard, also as Applicant has previously noted, Example D of

Harris et al. discloses an inoperative composition which resulted in an unacceptable amount of hydrolysis product, and in fact illustrates the indispensability of saccharide in the formulations of this reference. On the other hand, in the present invention as set forth in claim 16, the particular combination enables a stabilized formulation which does not contain saccharide. Applicants take the position that one of ordinary skill in the art would not have been motivated to add an insoluble alkaline-earth metal salt of hydrogen phosphate (Daniel et al.) to the formulation of Example D of Harris et al., since as indicated above, Example D is an inoperative composition which resulted in an unacceptable amount of hydrolysis product. Under the section of Finding of Obviousness/Rationale and Motivation (MPEP 2142-2143) beginning on page 9 of the Office Action, the Examiner states that it would have been obvious to combine the teachings of the two cited references to produce a stable ACE inhibitor composition because Harris et al. teach it is within the skill of the art to make a stabilized ACE inhibitor composition "comprising an ACE inhibitor, an alkali earth metal carbonate and a saccharide compound with a weight range between 5% and 90%" (Emphasis added) However, there is no motivation to add the dicalcium phosphate of Daniel et al. to the formulation of Example D of Harris et al. because Example D does not contain any saccharide compound. The Examiner has offered no obviousness-rationale or motivation for why one skilled in the art would have added the dicalcium phosphate of Daniel et al. to the formulation of Example D of Harris et al. which does not contain any saccharide compound.

For these reasons, Applicant takes the position that the presently claimed invention is clearly patentable over the applied references.

Therefore, the application is in condition for allowance, and such allowance is solicited.

Respectfully submitted,

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